ImmunoGen Presents Updated Findings from Phase 1 Study of IMGN632 at ASH Annual Meeting

December 9, 2019

Data Demonstrating Potential in AML and BPDCN Presented During Oral Presentation; Dose and Schedule Selected for Further Development

Preclinical Combination Data Also Presented; Support Further Evaluation of IMGN632 Doublets and Triplet in AML

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 9, 2019-- ImmunoGen, Inc., (Nasdaq: IMGN) a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that new safety and efficacy findings from the dose escalation and expansion of the first-in-human trial of IMGN632 in patients with relapsed/refractory acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) were presented in an oral session at the 61st American Society of Hematology (ASH) Annual Meeting in Orlando, Florida. Preclinical data related to IMGN632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax), and two "trial in progress" posters were also presented at the conference.

"The data presented at ASH demonstrate the potential of IMGN632 to offer a new treatment option for patients with AML and BPDCN," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "With the benefit of a comprehensive assessment of IMGN632's safety and efficacy across a wide range of doses and two schedules, we have selected a dose and schedule that demonstrate significant anti-tumor activity, favorable tolerability, and the convenience of a short infusion that can be administered in an outpatient setting. Together with the preclinical data on combining IMGN632 with azacitidine and venetoclax presented by our collaborators from MD Anderson, these updated clinical results provide a strong foundation for our ongoing expansion of IMGN632 monotherapy studies in BPDCN, AML, and ALL, and the recent initiation of our trial to evaluate IMGN632 combinations with azacitidine and venetoclax in relapsed and frontline AML, as well as IMGN632 as a monotherapy in minimal residual disease positive AML patients."

"We are particularly encouraged by the activity and tolerability of IMGN632 in heavily pre-treated patients, including a 40% ORR in relapsed and refractory de novo AML patients treated at the recommended phase 2 dose, and the responses in relapsed or refractory BPDCN patients previously treated with Elzonris® (tagraxofusp-erzs) and intensive chemotherapy," said Naval Daver, MD, Associate Professor in the Department of Leukemia at MD Anderson Cancer Center. "We look forward to continuing to evaluate IMGN632 as a monotherapy and in combination with azacitidine and venetoclax in doublet and triplet regimens in relapsed/refractory AML and frontline older AML."

PHASE 1 DATA ON IMGN632 AS A MONOTHERAPY IN AML AND BPDCN
Oral Presentation, Abstract #734
Updated key findings from the Phase 1 study of IMGN632 include the following:

Safety

- IMGN632 was administered to 95 patients over dose levels ranging from 0.015 to 0.45 mg/kg intravenously on the every 3 week schedule and 0.015 to 0.06 mg/kg on the fractionated day 1, 4, and 8 schedule every 3 weeks.
- IMGN632 displays a well tolerated safety profile and activity at doses up to and including 0.09 mg/kg per cycle.
- The most common treatment-related adverse event was infusion-related reactions (24% all grades, 8% grade 3); none required IMGN632 discontinuation.
- Single dose-limiting toxicities were seen at the highest dose levels tested (0.18-0.45 mg/kg): three reversible cases of veno-occlusive disease and one prolonged neutropenia; no patterns of hepatotoxicity or cytopenias occurred with doses below 0.18 mg/kg.
- Although no maximum tolerated dose was determined on either schedule, based on the efficacy, safety, and pharmacokinetic data generated, the dose and schedule of 0.045 mg/kg given on day 1 every 3 weeks has been selected as the monotherapy recommended Phase 2 dose.

AML Efficacy

- Across all dose levels and both schedules, of the patients assessable for efficacy (n=71), 38 (54%) had a reduction in bone marrow blasts and 13 (18%) achieved an objective response, including 2 complete remissions (CR) and 10 with incomplete recovery (CRi) and one morphologic leukemia free state (MLFS) in heavily pretreated patients. The vast majority of these responders (92%) had failed prior intensive therapies, including 3 with prior transplant, 69% had failed 2-3 prior lines of therapy, and 54% had an adverse risk classification.
- At the dose and schedule selected as the recommended Phase 2 dose (0.045 mg/kg Q3W), a 40% response rate was seen in relapsed and refractory patients with de novo AML, including 1 CR, 4 CRi, and 1 MLFS (with subsequent conversion to CRi).

BPDCN Efficacy

- 3 of 9 (33%) evaluable relapsed/refractory BPDCN patients achieved a response after a 1-2 doses of 0.045 mg/kg IMGN632 (1 CR, 1 CRi, and 1 partial remission); all three patients had received prior SL-401 (tagraxofusp-erzs), two had received intense multi-agent chemotherapy, and one had prior stem cell transplant.

PRECLINICAL DATA ON IMGN632 IN COMBINATION WITH AZACITIDINE AND VENETOCLAX

Poster Presentation, Abstract 1375

IMGN632 was evaluated in combination with azacitidine, and as a triplet with azacitidine and venetoclax in AML models, including patient derived xenografts (PDX). The addition of IMGN632 to azacitidine alone or to azacitidine plus venetoclax consistently led to reductions in tumor burden and to improved survival in these murine models. These data support clinical testing of the addition of IMGN632 to standard of care therapy including azacitidine, and azacitidine plus venetoclax in AML patients.

Additional information, including abstracts, can be found at www.hematology.org.

ABOUT IMGN632

IMGN632 is a CD123-targeting ADC in Phase I testing for hematological malignancies, including acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN), and acute lymphocytic leukemia (ALL). IMGN632 uses one of ImmunoGen's novel indolino-benzodiazepine (IGN) payloads, which alkylate DNA without crosslinking. IGNs have been designed to have high potency against AML blasts, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads.

ABOUT ACUTE MYELOID LEUKEMIA (AML)

AML is a cancer of the bone marrow cells that produce white blood cells. It causes the marrow to increasingly generate abnormal, immature white blood cells (blasts) that do not mature into effective infection-fighting cells. The blasts quickly fill the bone marrow, impacting the production of normal platelets and red blood cells. The resulting deficiencies in normal blood cells leave the patient vulnerable to infections, bleeding problems, and anemia. It is estimated that, in the U.S. alone, 21,380 patients will be diagnosed with AML this year and 10,590 patients will die from the disease.

ABOUT BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM (BPDCN)

BPDCN is a rare form of blood cancer that has features of both leukemia and lymphoma, with characteristic skin lesions, lymph node involvement, and frequent spread to the bone marrow. This aggressive cancer requires intense treatment often followed by stem cell transplant. Despite the recent approval of a CD123-targeting therapy, the unmet need remains high in the relapsed/refractory setting.

ABOUT CD123

CD123, the interleukin-3 alpha chain, is expressed on multiple myeloid and lymphoid cancers including AML, BPDCN, ALL, chronic myeloid leukemia, and myeloproliferative neoplasms. With limited expression on normal hematopoietic cells, rapid internalization, and expression on AML leukemia stem cells, CD123 is a validated therapeutic target, with the recent approval of a CD123-targeting therapy for BPDCN.

ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to “target a better now.”

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements based on management's current expectations. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

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